a period of 36 months of which six were emergencies. The mean age was 64.6 years. 26 patients were ASA Grade III or more.
Methods: Risk factors were hypertension (n=20), hypercholesterolaemia (n= 17), smoking (n=14) and ischaemic heart disease (n=9). 17 procedures were for thoracic abdominal aneurysms type three, 7 thoraco-abdominal aneurysms type four, 4 aortic dissection Type B, 1 infantile adult aortic coarctation and 2 spontaneous supra visceral aortic ruptures. Seven patients underwent a one/ two stage hybrid debranching of visceral vessels followed by TEVAR. Fourteen patients underwent chimney or Snorkel Endografting of Subclavian or renal vessels. Two patients underwent multilayered stenting for thoraco-abdominal aneurysms with visceral involvement. One patient had a CPS stent for infantile adult coarctation.
Results: Primary endpoints were 6% mortalities within 30 days for the two acute emergencies of which one was a HIV patient with syphilitic aneurysm. 30 day morbidity was one acute tubular necrosis and one lower respiratory tract infection. Aneurysm free survival time was 19months. No patients developed aneurysm rupture, paraplegia or stroke. Four cases of endoleak were witnessed however no aneurysm expansion was experienced. Two patients required re-intervention for graft migration.
Conclusion: We display from our experience that minimal invasive techniques with TEVAR and debranching, chimney, snorkel and multilayered stent grafting of visceral vessels is safe, prudent and economically viable. The development of multilayered stenting technique looks ever promising for future management of complex aortic pathologies.

TCT-558

5-year THUNDER Follow-Up: Patients with PAD Treated with Uncoated Versus Paccocath Paclitaxel Coated Balloons

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Background: Restenosis remains the primary limitation following femoropopliteal PTA, with rates of 40 - 60% at 1 year. Multiple prospective, randomized studies (FemPac, THUNDER) evaluated the concept of localized antiproliferative drug delivery for the prevention of restenosis in the peripheral arteries using Paccocath® paclitaxel coated balloons versus uncoated balloons. These studies demonstrated favorable results for the Paccocath balloon cohort on late lumen loss (LLL) and target lesion revascularization (TLR) rates up to 2 years post index procedure. The purpose of this study is to assess long term efficacy results of the Paccocath balloon versus an uncoated balloon.
Methods: Patients who were originally enrolled and treated in the THUDNER trial were re-consented to enable the 5-year follow-up data collection. The clinical data (e.g., TLR, deaths, amputations, bypass surgery, etc.) and angiograms were collected up to 5 years follow-up. The 5-year clinical and angiographic data analyzed by an independent angiographic core laboratory were compared to the previously reported baseline, 6, 12, and 24 months data to assess the long-term effect of the Paccocath balloon.
Results: The data is currently being monitored. However, the preliminary analysis demonstrated that TLR rates are significantly lower in the Paccocath balloon group compared to the uncoated balloon group. As confirmed by 5-year follow-up visits, approximately 70% of patients in the Paccocath balloon group did not require any additional target lesion treatment (e.g., TLR) from the time of the index procedure compared to approximately 30% of patients in the uncoated balloon group. In addition, the time to the first TLR from the index procedure is significantly longer in the Paccocath balloon group compared to the uncoated balloon group. Besides clinical and angiographic data, the finding that severe dissections left with no stent implantation in the Paccocath group was a predictor of favorable long term outcomes will be presented at TCT 2011.
Conclusion: The Paccocath balloon demonstrated superior long-term results compared to the uncoated balloon when used for the treatment of femoropopliteal arteries.

TCT-559

Impact of Angiosome Approach on Clinical Outcomes of Endovascular Therapy in Patients with Critical Limb Ischemia Presenting with Isolated Below-the-Knee Lesions

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Background: We investigated whether the angiosome concept is useful in endovascular therapy (EVT) of critical limb ischemia (CLI) patients with isolated below-the-knee (BTK) lesions and assessed factors influencing major amputation (MA) in direct and indirect groups.
Methods: We analyzed 369 limbs from 329 consecutive patients (male=224, age; 70±11 years) with ischemic ulceration/gangrene, presenting with isolated BTK lesions (Rutherford 5: 270 limbs and 6: 99 limbs, respectively). We classified these patients into direct (n=200) and indirect (n=169) groups depending on whether feeding artery flow to the site of ulceration/gangrene was either successfully achieved or not based on the angiosome concept. Rates of amputation-free survival (AFS), freedom from major amputation (MA) and from major adverse limb events (MALE) were compared between direct and indirect groups by Kaplan-Meier analysis and log-lank test. Multivariate analysis was performed to explore the independent determinants of limb salvage in the direct and indirect groups.
Results: During follow-up (mean 18±16months), the overall limb salvage rate was 81% (300/369), and death occurred in 36 % (119/329) of patients. Rates of AFS (39±7 vs. 30±7, p=.04), and freedom from MA (79±4 vs. 72±4, p=.05) and from MALE (46±6 vs. 29±8, p=.02) were significantly higher in the direct group than in the indirect group for up to 4 years after index procedure. After multivariate Cox proportional analysis, HbA1c (hazard ratio [HR], 1.4; 95% confidential interval [CI]: 1.1-1.9; P=0.007) and administration of cilostazol (HR, 0.27; 95% CI, 0.11-0.68 1.1; P=0.0055) in the direct group and C-reactive protein level (HR, 1.4; 95% CI, 1.1-1.7; P=0.001) in the indirect group were the independent factors associated with MA by multivariate analysis.
Conclusion: Achieving direct flow by EVT based on the angiosome concept in CLI patients with isolated BTK lesions is important for AFS, FFMA and FFMALE. Limb salvage factors appear to differ between patients with and without direct flow from the feeding artery after EVT.

TCT-560

Results of the CONFIRM II Study Demonstrate the Value of Orbital Technology in Effectively Restoring Flow in Patients with Calcified Infra-Inguinal Disease

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Background: While guidelines for the diagnosis and management of patients with peripheral arterial disease (PAD) are well established, appropriate use of recently introduced endovascular therapies is less defined. Clinical data from a real-world patient population is needed to determine device utility and procedure success. The CONFIRM Series was designed to validate the efficacy of orbital treatment in patients with obstructive infra-inguinal disease.
Methods: The CONFIRM II Study is a prospective registry of 1,127 consecutive patients with 1,712 infrainguinal and infrapopliteal lesions treated with the latest orbital crown technology, Predator 360 (Cardiovascular Systems, Inc., St. Paul, MN). It follows the CONFIRM I Study that evaluated the effectiveness of earlier device iterations. Descriptive acute procedural data was collected by 153 investigators at 122 institutions.
Results: Patients were 70.7 years; 61.5% male. Comorbidities were renal disease (35.4%), current or previous smokers (69.8%), diabetes (57.8%), CAD (73.2%), HTN (91.2%), and hyperlipidemia (79.2%). Lesion morphology: mild to severe calcium (90%). Lesion location: superficial femoral and other proximal vessels (52%), popliteal (17%), and tibials (31%). Average lesion length: 72 mm. Device run time averaged 103 seconds per patient, followed by angioplasty (mean 5.44 atms) in 86% of lesions. Bail-out stenting due to dissection: 2.5% of lesions. Average stenosis: 87.8% pre-procedure, 33.9% post orbital and 9.6% post adjunctive. Procedural events included minor and major dissection (7.8%), perforation (0.4%), slow flow (3.8%), abrupt closure (1.4%) and distal macro embolization (1.9%).
Conclusion: The CONFIRM II Study validates the use of the latest iteration of orbital technology in restoring flow by changing lesion compliance, thus allowing low-pressure balloon angioplasty with limited complications and reduced need for bailout stenting. This data contributes to a large and growing database showing predictable, repeatable results of orbital technology in small, calcified vessels.

TCT-561

New Conformable Thoracic Stentgraft (SG) – Apposition Scoring in the Thoracic Aorta Near the Arch

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Background: Current thoracic SG complies poorly with the curvature of the aortic arch. Two new conformable SG were introduced to the European market. Due to the different designs it is postulated, that the new SG are allowed for better apposition to the aortic wall. We now report the first clinical experience with this technique in 45 patients.
Methods: Since 6/2009, 45 pts (33 m; 67.5(45-85)yrs) were treated for descending thoracic aorta pathologies near the arch (TAA:27, acute dissection:9, chronic dissection:7, trauma:2) with new thoracic SG (Zenith® TX2™Pro-Form™,n=10; Conformable GORE TAG®,n=35). Additional arch debranching was performed in 17 cases. Evaluating the post-operative CT imaging apposition of the SG to the aortic wall was scored (1 point (excellent): circular, 2 points (good): >2/3 circumferential, gap to inner curve <1cm; 3 points (bad): <2/3 circumferential, gap inner curve >1cm; 4 points: type Ia endoleak).
Results: The modified thoracic SG were correctly deployed in 42/45 pts. In one patient,

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the proximal edge of the SG (C-TAG) slid into the orifice of the LCA resulting in occlusion. The subsequently performed LCA-RCA-bypass resolved the perfusion without cerebral deficit. In two another pts distal migration of the SG (C-TAG) was followed by secondary conversion with open thoracic tube graft repair (n=1), or arch debranching and subsequently performed TEVAR(n=1). Proximal stent graft apposition was excellent in 29/42 cases, good in 12/42 cases, and bad in 1 case. No type I endoleak was detectable. In comparison to matched cases treated with former generation of SG the apposition scoring was significantly better.
Conclusion: The newly available thoracic SG both improves proximal apposition of the device at the inner curve of the aortic arch. More data and longer follow-up are required to confirm the applicability of this technique.

TCT-562

Retrograde transpedal access for below-the-knee chronic total occlusions after failed anterograde recanalisation

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Background: The purpose of the study was to evaluate the acute success and clinical impact of retrograde transpedal access for retrograde below-the-knee artery (BTK) chronic total occlusions (CTO) after failed attempts to re-enter the true lumen in the anterograde femoral approach.
Methods: The clinical and angiographic data of 28 consecutive patients with CLI treated by retrograde transpedal recanalisation between 2010 and 2011.02 were evaluated in a pilot study. Patients received daily aspirin, clopidogrel during the procedure. We examinated the one-month major adverse events (MAEs). Clinical success was defined as relief of resting pain, healing of ulceration or avoidance of amputation. After re-entry to the true lumen failed or the guidewire passage was unsuccesfull during anterograde approach, the anterior tibial or posterior tibial artery was punctured with a transradial 20 G needle under fluoroscopic guidance and coronary guidewire was advanced in the artery.
Results: 26 (92.8%) of 28 procedures were finished successfully with a good angiographic result and flow. The failure rate was 7.2% (1 unsuccessfull puncture and 1 failed reentry). Balloon angioplasty was performed in all successfull interventions and provisional stenting was done in 7 patients (27%). The procedure was finalised with anterograde rotational atherectomy in one case (3.5%) due to inability to pass the balloon. No major access site complications occured; however three transient spasm was found in the investigated population (11%). Technical and clinical success was observed in 26 (92.8%) and in 25 patients (89.2%). The MAE in the investigated population was 3.57% (2 major amputations).
Conclusion: Failed antegrade attempts to recanalise CTO-s of BTK vessels can be salvaged using a retrograde transpedal access, with a low complication rate. This technique could be valuable for patients with critical limb ischemia due to popliteal and infrapopliteal occlusions once larger studies with follow-up confirm safety, efficacy, and clinical benefit.

TCT-563

Five-Year Trial of TASC II Type C/D Lesions Undergoing Subintimal Angioplasty or Bypass Surgery Based on Plaque Echolucency

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Background: 5-year study comparing the effectiveness of subintimal angioplasty (SIA) to bypass grafting (BG) for treatment of TASC II type C/D lesions in patients with critical limb ischemia (CLI).
Methods: Of 1076 patients referred with PVD from 2002 to 2007, 206 SIAs in 190 patients and 128 bypass grafts in 119 patients were enrolled in the study. All patients had rest pain and/or tissue loss. Primary endpoints were survival free from amputation and sustained clinical improvement. Secondary endpoints were major adverse events (MAE), the binary restenosis rate, freedom from TLR, and a special quality-adjusted life year (QALY) endpoint (Q-TWiST) that incorporated both length and quality of life to evaluate treatments
Results: At 5 years, clinical improvement was sustained in 82.8% of the SIA group versus 68.2% of the BG patients (p50.106). Five-year all-cause survival was similar for SIA (78.6%) and BG (80.1%; p=0.734), as was amputation-free survival (SIA 72.9% versus BG 71.2%;p=0.976). Hyperfibrinogenemia (p=0.009) and C-reactive protein (p=0.019) had negative effects on survival without amputation. Five-year freedom from binary restenosis rates were 72.8% for SIA versus 65.3% for BG (p=0.700). While the 5-year freedom from TLR rates (SIA 85.9% versus BS 72.1%, p=0.262) were not statistically significant, the risk of MAE (p<0.002) and length of hospital stay (p<0.0001) were significantly reduced. Q-TWiST significantly improved (p<0.001) and cost-per-QALY was reduced with SIA. The 5-year risk of re-intervention (p>0.05) and mean number of procedures (p=0.078) were similar.
Conclusion: Five-year freedom from MAE was enhanced by 20% in the SIA group, with substantial cost reduction and better Q-TWiST. SIA is a minimally invasive technique that expands amputation-free and symptom-free survival. SIA is a paradigm shift in the management of CLI.

TCT-564

Vertebral Angioplasty Stenting. Are Protection Devices Useful?

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Background: It is now clear that atheroemboli are the rule in any intervention in atherosclerotic disease and seems the root cause of many procedural complications.Embolic Protection Devices(EPD) are largely used to reduce the nb of cerebral emboli during carotid angioplasty stenting(CAS).Recent studies have shown a high incidence of emboli during Vertebral Angioplasty Stenting(VAS) & a comparable frequency & amount of captured emboli during VAS and carotid angioplasty stenting. Neurological complications after VAS are not frequent but could be devastating.So the use of EPD for VAS may be advisable & should reduce the neurological complications during VAS
Methods: We retrospectively determined rates of technical success & 1 month stroke and death associated with stent placement by using EPD (Filterwire)and a new filter Fibernet (Lumen Biomedical) in pts with symptomatic ostial VA stenoses. Technical success was defined as successful EPD deployment and stent placement,successful EPD retrieval & a residual stenosis<30%. 30 day outcomes included any stroke & death. The new EPD (Fibernet) allows capture of debris of 40µ without compromising the flow. Its retrieval catheter is an aspiration catheter allowing meticulous cleaning of the vessel and of the dilated area
Results: In a series of 102 VAS 10 pts treated with EPD. Mean age 69 y.(63-80).♂:8, left6. Mean% stenosis 80,9±6,8. Mean arterial Ø:4,8±0,5mm. Femoral approach used in all cases. Filterwire:8 pts,Fibernet:2. Technical success was achieved for the 10 pts. Postprocedure residual stenoses:4±3%. Visible debris were removed in 70%of cases (Filterwire:5 and Fibernet:2).Filter deployment time:10mm (7-13mm).No stroke or death observed at 1 month. With Fibernet mean debris area:184 mm2.(aspirated debris:114mm2,debris in the filter70 mm2) Debris analysis will be reported. These results are comparable to the results obtained in CAS
Conclusion: The present study demonstrates the feasibility and safety of VAS using EPD. Further studies are required to determine the exact role of EPD and their indications in VAS. It seems that the results obtained in VAS are comparable to those obtained after CAS.

TCT-565

The Role of Pull-Back Pressure Gradient in Percutaneous Transluminal Angioplasty for Central Vein stenosis in Dialysis Patients

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Background: The severity of residual stenosis (RS) in central vein stenosis(CVS) sometimes hard to be accurately measured by angiographic image. Because of intracoronary pressure is good alternative parameter in coronary intervention, the role of pull-back pressure measurement in percutaneous transluminal angioplasty for CVS was evaluated.
Methods: This study retrospectively reviewed consecutive 94 dialysis patients asked for management of CVS which were divided into two groups by aniographic image or post-intervention pressure gradient (PG), and followed up long term clinical outcomes. 12-month patency rate between groups were compared and analyzed.
Results: The 94 patients consisted of 47 males and 47 females. There were divided into two groups which included 63 cases in successful group (RS<30%) and 31 cases in acceptable group (50%>RS>30%) by aniographic criteria, or which included 51 cases in PG<5 mmHg(PG1 group) and 43 cases in PG>5mmHg(PG2 group) by measured pullback PG. the baseline characteristics and parameters during intervention between groups were almost no statistical difference. 12-month patency rate in successful group vs. acceptable group were 54% vs. 39%(P= 0.167), while in PG1 group and PG2 group were 60% vs 37% (P= 0.048). Further, subgroup analysis between PG1 group vs. group accordance to the criteria of accepted group plus PG2 group were 60% vs 29%(P=0.058).

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